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## I. INTRODUCTION

The TriService Nursing Research Program (TSNRP) Call for Proposals introduces the Program, announces the availability of grant funds for FY 2004, and provides application guidelines for these funds. An electronic version of this document can be accessed online through <a href="http://www.usuhs.mil/tsnrp">http://www.usuhs.mil/tsnrp</a>.

This Call for Proposals contains information that not provided in previous Calls, including the acceptance, between November 2003 and April 2004, of applications for the Graduate Research Award. Military nurses considering application for TSNRP funding should become familiar with each section of this Call for Proposals. Applicants should be mindful of requirements pertinent to the award for which they are applying and their military status.

All forms needed to apply for TSNRP funding can be accessed online through <a href="http://www.usuhs.mil/tsnrp/forms">http://www.usuhs.mil/tsnrp/forms</a>. Appendix C contains a table showing the forms needed for each type of award application. Some TSNRP application forms, and samples of application forms, are provided in Appendix C. Applicants should use only the most current application forms.

Please contact the TSNRP office with questions, or for additional information:

TriService Nursing Research Program 4301 Jones Bridge Road Bethesda, MD 20814 Phone: 301-295-7077

Phone: 301-295-7077 Fax: 301-295-7052

E-mail: tsnrp@usuhs.mil

## II. BACKGROUND

The mission of the TSNRP is to provide resources for the conduct and use of research to foster excellence in military nursing care. Since its inception through congressionally appropriated funding in 1992, the TSNRP has evolved through the earnest endeavor of military nurses. Military nurse investigators have increasingly invested their time and expertise in this program. Success of the program is evidenced by the positive outcomes of research studies conducted to improve the health of service members and their military beneficiaries. More than 240 research studies in basic and applied science have been funded since 1992. General topics that have been investigated with TSNRP funding include: military readiness and deployment, skill sustainment, evacuation and transportation, nursing care in unique military environments, military nursing histories, health promotion and disease prevention, men's and women's health issues, managed care environments, case management, nurse-run clinics, telehealth, and econometrics. Abstracts for all TSNRP-funded studies are available online at <a href="http://www.usuhs.mil/tsnrp/funded/index">http://www.usuhs.mil/tsnrp/funded/index</a>. The TSNRP's award history is described in Appendix A.

Military nursing's unique perspective for the care of its beneficiaries requires not only scientific investigational activities, but also rapid dissemination and use of study results. Dissemination of findings to nurses in a global setting is a particular challenge that has been met by this program. Results of TSNRP studies have been reported in refereed nursing and other health discipline journals, including: American Journal of Critical Care, Cancer Nursing, Clinical Nursing Research, Journal of Interferon and Cytokine Research, Journal of Nursing Administration, Military Medicine, Nursing Science Quarterly, and Western Journal of Nursing Research.

Findings from TSNRP-funded grants have been presented at military, regional, national, and international conferences, including those of the following organizations: Aerospace Medical Association, American Association of Critical Care Nursing, American College of Preventive Medicine, Association of Military Surgeons of the United States, Midwest Nursing Research Society, Phyllis J. Verhonick Army Research Conference, State of the Science Congresses, Sigma Theta Tau International, Southern Nursing Research Society, US Army Nurse Corps, and the Western Institute of Nursing.

The TSNRP works in concert with schools of nursing at universities and colleges across the country. Faculty at these academic institutions include non-military nurse researchers who offer research and content expertise, and reserve and retired military nurse researchers who offer unique military perspectives in addition to subject expertise. Affiliations with schools of nursing foster relationships between nurse researchers and help to sustain the cadre of military nurse researchers. Partnerships with other research institutions and organizations, both military and civilian, continue to be forged to maximize the success of the program.

The TSNRP is pursuing an aggressive research agenda focusing on topics most relevant to military nursing practice, and in alignment with the Services' strategic goals. It is imperative that the research conducted today has application for military beneficiaries tomorrow.

## III. RESEARCH PRIORITIES

In 2001, TSNRP identified five areas on which to focus its research efforts. In 2002, these research priorities were refined based on current Service-specific needs.

- **Deployment Health:** Research designed to examine physiological and psychosocial factors of individuals and families that affect readiness before, during, and after deployment, and the provision and evaluation of nursing care in the military environment.
- **Developing and Sustaining Competencies:** Research designed to identify the methods of developing nursing expertise in multiple venues. This research may include the identification of the continuum of nursing skills during peacetime and wartime, factors that enhance the genesis, maturation, and retention of those skills, as well as the effect of mentoring on that continuum
- Recruitment and Retention of the Work Force: Research designed to identify factors
  associated with recruitment and retention of nursing personnel in the military health care
  system.
- Clinical Resource Management: Research designed to identify and test staffing models for the provision of safe and cost-effective care.
- Military Clinical Practice and Outcomes Management: Research designed to inform
  military nursing practice as well as to identify those interventions that have been supported
  by findings or previous research, and found to be efficacious. Outcomes research is an
  important scientific methodology developed to examine the end result of patient care
  strategies, including non-traditional methods and perspectives from evaluation research,
  epidemiology, and economic theory.

The TSNRP supports both quantitative and qualitative methodologies.

Applicants should familiarize themselves with the TSNRP's previously funded research. Details on these studies are available online at <a href="http://www.usuhs.mil/tsnrp/funded/index.html">http://www.usuhs.mil/tsnrp/funded/index.html</a>.

## IV. ELIGIBILITY AND AWARDS

#### A. WHO MAY APPLY

Active Duty, Reserve, and National Guard Nurse Corps Officers are eligible to apply for TSNRP funding. Retired Nurse Corps Officers are also eligible for TSNRP funding, however, there are some eligibility limitations and application requirements for retired military nurse scientists. There are also other eligibility requirements specific for award categories and the experience and military status of the Principal Investigator (see below).

- 1. TSNRP promotes the mentoring of new and junior military nurse researchers as a way to achieve its goal of expanding the cadre of military nurse researchers. TSNRP considers a new and/or junior investigator to be a *novice* investigator, that is, a Masters-prepared nurse clinician or Doctoral-prepared military nurse with no or limited experience in conducting a research study. A *mentor* is defined as an experienced nurse researcher who supports, guides, and assists a new or junior investigator. There are mentoring requirements for the following applicants:
  - Investigators applying for Novice Investigator Awards
  - Investigators who are retired Nurse Corps Officers
  - Investigators applying for Research Fellow Awards
  - Investigators applying for Graduate Research Awards

TSNRP highly encourages new or junior investigators seeking research experience to apply for the Novice Investigator Award.

2. Active duty and Reserve graduate students are highly encouraged to apply for a Graduate Research Award to conduct their dissertation or thesis.

Additional eligibility requirements and award limits are shown in the table on the following page.

## **B. FY 2004 AWARD CATEGORIES AND ELIGIBILITY REQUIREMENTS**

The TSNRP offers eight funding categories: Novice Investigator Award; 1-, 2-, 3-Year Award; Pilot Project Award; Research Fellow Award; Graduate Research Award; and Fast Track Award. *Note the funding limit for the 3-Year Award has been raised to \$500,000 in total costs.* 

Novice Investigator Award	Purpose: To provide military nurse clinicians with limited research experience support for a study that is modest in scope, or as a first phase of a larger project.  Award: Up to \$100,000 in direct costs for support of a 1-year study.  Eligibility: Master's- and doctoral-prepared military nurse clinicians with limited experience in conducting a research study.
1- and 2-Year Award	Award: Up to \$450,000 total costs (direct plus indirect costs).  Eligibility: All Active Duty, Reserve, National Guard and Retired* Nurse Corps Officers with research experience.
3-Year Award	Award: Up to \$500,000 total costs (direct plus indirect costs).  Eligibility: All Active Duty, Reserve, National Guard and Retired* Nurse Corps Officers with research experience.
Pilot Project Award	Purpose: To provide preliminary data for a future research project  Award: Up to \$30,000 in direct costs to support a 1-year study to provide preliminary data to support the development of future projects.**  Eligibility: All Active Duty, Reserve, National Guard and Retired* Nurse Corps Officers.
Research Fellow Award	Purpose: To facilitate training of military nurses interested in research and expand the skills of experienced military nurse researchers.  Award: Up to \$75,000 in direct costs for support over a 1-year period to provide mentored experience to Masters- and Doctoral-prepared military nurses, for the development of specific research-related skills.  Eligibility: Masters- and Doctoral-prepared Active Duty and Reserve Nurse Corps Officers. Retired Nurse Corps Officers may not apply.
Applications for the above of	6 award categories accepted in November and March of each fiscal year.
Graduate Research Award	Purpose: To support a dissertation/thesis research project.  Award: Up to \$30,000 in direct costs to support a 1- or 2-year project.  Eligibility: Active Duty and Reserve students pursuing a Masters or Doctoral degree in nursing. Retired Nurse Corps Officers may not apply. Only one award funding per thesis and dissertation.
	Applications accepted November 2003 through April 2004.
Fast Track Award	Purpose: To facilitate rapid implementation of short-term research of emerging service-specific questions or concerns.  Award: Up to \$25,000 in direct costs to support a period not to exceed 15 months.  Eligibility: Experienced Active Duty Nurse Corps researchers only. Students, novice researchers, and retired military nurses may not apply.  Applications accepted four times each fiscal year.

<sup>\*</sup>See mentoring requirements for Retired Nurse Corps Officers in Section VII: Proposal Preparation, page 14

The exact amount of funding awarded to an individual grant depends on the purpose and goals of the application, and the availability of funds.

<sup>\*\*</sup>TSNRP highly recommends pilot work to substantiate feasibility and instrument reliability before embarking on a large-scale study.

#### C. APPLICANT ORGANIZATIONS

Awards are made to institutions, not individuals. Although the PI writes the application, implements the research, and disseminates the results, the monetary award is made to an institution known as the applicant organization. The applicant organization assumes responsibility for the execution of the grant.

As the granting authority for the TSNRP's Congressionally appropriated funds, the Uniformed Services University of the Health Sciences (USUHS) can award grants only to organizations outside the Federal sector. Typically, applicant organizations are academic institutions or non-profit organizations. Investigators can submit their application through a non-Federal applicant organization of their choice. Appendix B contains information on non-profit organizations frequently used by military personnel.

## V. FUNDING CYCLE

The deadline for the submission of applications for Novice Investigator, 1-, 2-, 3-Year, Pilot Project, and Research Fellow Awards is **4 P.M. EST, 2 March 2004**. All applications submitted for these awards will undergo the same review process, and follow the same funding cycle.

# FUNDING CYCLE Novice Investigator, 1-, 2-, 3-Year, Pilot Project, and Research Fellow Awards

Letter of Intent Deadline	6 January 2004
<b>Application Deadline</b>	2 March 2004 by 4 P.M. EST
Scientific Review	April 2004
Programmatic Review	May 2004
Funding Decision	June 2004
Notification of Funding	July 2004

## FUNDING CYCLE Graduate Research Awards

With this FY04-B funding cycle, Graduate Research Awards will be **accepted between November 2003 and April 2004**. See Section VII: Application Submission, b. Submission
Requirements. Applications submitted for Graduate Research Awards will follow a funding
cycle and review process independent of those for the other awards. See Section VIII: Proposal
Evaluation, 2. Review of Graduate Research Awards.

## FUNDING CYCLE Fast Track Awards

The Fast Track Award has been designed to allow for quarterly submissions in January, April, June, and October. Applications submitted for Fast Track Awards will follow a funding cycle and review process independent of those for the other awards.

Letter of Intent Deadline	**		Funding Decision	Earliest Start Date		
5 December 2003	21 January 2004	February 2004	March 2004	If approved for funding, and		
2 March 2004	2 March 2004 <b>6 April 2004</b>		June 2004	funds are available,		
4 May 2004	1 June 2004	July 2004	July 2004	awards will be		
7 August 2004	5 October 2004	November 2004	December 2004	immediately negotiated.		

See Section VIII: Proposal Evaluation, 3. Review of Fast Track Awards.

## VI. APPLICATION SUBMISSION

#### A. INTENT TO SUBMIT AN APPLICATION

Investigators are highly encouraged to notify the TSNRP of their interest in applying by submitting a Letter of Intent (LOI). The LOI is not a commitment to submit an application. TSNRP may provide guidance in response to a LOI. LOIs may be submitted electronically through the TSNRP web site, <a href="http://www.usuhs.mil/tsnrp/forms/index.html">http://www.usuhs.mil/tsnrp/forms/index.html</a>, as a paper copy mailed to the address below, or faxed to 301-295-7052 (see Appendix C for LOI forms).

#### **B.** SUBMISSION REQUIREMENTS

Application requirements are determined by the award category. The application will consist of TSNRP forms, and Public Health Service (PHS) forms, either PHS 398 forms (revised 5/01), PHS 416-1 forms (revised 11/02), or a combination of both. A table showing the application forms required for each award category is provided on page 10. All applications must be accompanied by TSNRP forms revised 7/03. A **complete application** includes:

- One signed original of the TSNRP forms and appropriate PHS forms, with appendices
- Two copies of the entire original, including appendices
- One electronic copy (IBM compatible diskette or CD-Rom only) of the application in Microsoft Word format. The electronic copy does not need to include the appendices.
- <u>Three</u> electronic copies (IBM compatible diskette or CD-Rom only) of only the Research Plan

The application packet should be secured with rubber bands (no staples, clips or binders). All forms are available online at http://www.usuhs.mil/tsnrp/forms/index.html.

The complete application for Novice Investigator, 1-, 2-, 3-Year, Pilot Project, and Research Fellow Awards must be submitted by 4 P.M. EST on 2 March 2004 to:

CDR Patricia W. Kelley, NC, USN DNSc, RN, FNP, GNP Director TriService Nursing Research Program 4301 Jones Bridge Road Bethesda, MD 20814-4799

The complete application for **Graduate Research Awards may be submitted between November 2003 and April 2004 to the address above.** Applications received after the 30 April 2004 deadline will be considered in the FY05 funding cycle.

The complete application for Fast Track Awards must be submitted by 4 P. M. EST on 21 January, 6 April, or 1 June 2004 to the address above.

Applications that are not received by the stated deadline are considered late applications. Late applications and/or applications exceeding the funding award limit will be returned to the applicant and will not be considered for review.

### C. SUBMISSION OF DUPLICATE APPLICATIONS

The TSNRP discourages the submission of an application that is a duplicate of an application in concurrent review by another funding agency.

## VII. PROPOSAL PREPARATION

#### A. GENERAL APPLICATION GUIDELINES

Investigators are encouraged to submit rigorous scientific proposals that convey military relevance, and relevance to the TSNRP's research focus areas (see Part III). The proposal should demonstrate logical consistency and clarity throughout (i.e., purpose, statement of specific aims, review of literature, theoretical framework, research questions/hypotheses, design, data collection, and data analysis).

When preparing the application, applicants should pay utmost attention to detail, ensuring that all parts of the proposal are consistent, error-free, and complete. The following guidelines should be used to format an application:

- Study title must be limited to a maximum of 56 characters.
- Single sided and single spaced.
- Margins, in all directions, must be at least ½ inch, or according to the application form pages (which are pre-formatted).
- Font size must be no smaller than 12 point.
- No more than 6 lines of type within a vertical inch.
- Page limitations and content requirements as per the PHS 398 instructions

Applications must be complete and accurate at the time of submission. An application will be returned without review <u>if it exceeds the funding award limit</u>, is illegible, fails to meet the guidelines, or presents insufficient material to permit an adequate review. **Supplementary or corrective material may not be submitted after the deadline, unless the TSNRP Director agrees to accept this information.** 

#### **B.** APPLICATION RESUBMISSION

PIs are limited to submitting two revisions of an application. The PI should identify whether the current grant application represents a revision of an application previously submitted for TSNRP funding. Resubmission is an opportunity for the PI to address comments from previous scientific and programmatic reviews, and to state how the recommendations were considered when preparing the revised application.

All revised applications must include an introduction that is not to exceed three pages. In the introduction, list each area of concern noted in the reviews (scientific and programmatic) for the previous application, and provide a detailed response to each concern. Summarize clearly the changes that have been made in the revised application. Do not include an extensive description of each change in the introduction. In the body of the application, highlight paragraphs with significant changes since the previous application by bracketing, indenting, or changing the typography. Do not underline, bold type, or shade changes. If the changes are so extensive as to include most of the text, this exception should be explained in the introduction to the revised application. Refer to the PHS 398 instructions for guidelines on preparing a revised application.

All information from a previously submitted application, including reviewer critiques, is made available to reviewers for consideration during the scientific and programmatic review process.

#### C. APPLICATION FORMS

The table below outlines the forms needed for a complete application for each type of award. All forms are accessible through the TSNRP web site <a href="http://www.usuhs.mil/tsnrp/forms/index.html">http://www.usuhs.mil/tsnrp/forms/index.html</a>.

#### Applications forms needed for each award category

						PHS :	398 F	ORMS							PHS 41	6-1 Forn	ns (NRS	<b>A</b> )	
Award	TSNRP Forms	Face Page	Abstract Page	Table of Contents	Detailed Budget	Entire Budget	Biographical Sketch	Other Support	Resources	Research Plan	Checklist	Personal Data	Form Page 2	Table of Contents Form Page 3	Scholastic Performance Form Page 4	Background Form Page 5	Research Form Page 6	Bio Sketch of Sponsor Form Page 7	Facilities & Commitment Form Page 8
Novice Investigator	✓	✓	<b>✓</b>	<b>√</b>	<b>✓</b>	✓	✓	✓	✓	✓	✓	✓							
1- and 2- Year	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓							
3 Year	<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>✓</b>	✓	<b>✓</b>	✓	✓	<b>✓</b>	✓							
Pilot Project	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓							
Graduate Research	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			<b>√</b>	<b>√</b>		✓	✓
Research Fellow	✓	✓			✓	✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	✓
Fast Track	✓	✓	✓	<b>√</b> *	✓	✓	✓	✓	✓	✓	✓	✓							

<sup>\*</sup>Modified PHS 398 Table of Contents form specific to the Fast Track Award

#### 1. All Applicants

Applicants of all award categories must complete the following two TSNRP Forms.

#### a. Grant Application Cover Sheet

All proposals must have a completed TSNRP Grant Application Cover Sheet (see Appendix C) as the first document of the application. The PI's name, military rank, military unit, full mailing address to include facsimile, and e-mail, and (if applicable) civilian title(s) and work position are required. The PI must indicate the Award Category being requested (see Part IV.B), and categorize the proposal according to the TSNRP Research Priorities (see Part III). PIs who have previously received TSNRP funding must attach on a separate page dissemination of research findings from their TSRNP-funded research

#### b. Relevance to Military Nursing Form

The Relevance to Military Nursing form follows the Cover Sheet (see Appendix C). In the space provided, the Principal Investigator should fully describe how the proposed research would expand the body of military scientific knowledge and/or military nursing practice.

#### 2. Novice Investigator, 1-, 2-, 3-Year, and Pilot Project Applicants

Applicants for these awards must complete PHS 398 forms, revised 5/01, and updated 29 September 2003. PHS 398 forms, and instructions for completing the forms, are accessible online through the TSNRP web site <a href="http://www.usuhs.mil/tsnrp/forms/index.html">http://www.usuhs.mil/tsnrp/forms/index.html</a>. Applicants are advised that there are additional TSNRP-specific instructions for some PHS 398 forms, for example, Budget Forms, Biographical Sketch Format Page, Other Support Format Page, etc., and the application instructions contained in this Call for Proposals supercede instructions for the PHS 398 forms.

The PI's name and rank should be listed at the top right corner of each PHS 398 page, except for the face page. Additional general instructions are provided below.

#### a. Face Page

Since the applicant organization is ultimately responsible for the implementation and administration of the research, the signing official at the organization and the PI must both sign the Face Page (see Appendix D). The signing official's signature is considered certification of the information contained within the application, the budget information in particular, and provides assurance that appropriate mechanisms are in place to manage and monitor the grant. Applications submitted with only the PI's signature on the Face Page will be returned without review.

#### b. Description, Performance Sites, and Personnel (Abstract page)

#### 1) Description

This section is also known as the research "abstract." Follow the instructions listed on the PHS 398 form. In the space allowed, cite key areas of the research, for example, the problem to be examined, theoretical framework, population or sample, design, procedures, intervention, data analysis plan, measurements, etc.

#### 2) Performance Site

A performance site is a location where data are collected. The performance site may or may not be the same as the PI's assigned duty station or academic site. A study may have multiple performance sites (see example below).

PERFORMANCE SITE(S) (organization, city, state)						
Naval Medical Center	San Diego, CA					
Madigan Army Medical Center	Tacoma, WA					
Brooke Army Medical Center	San Antonio, TX					
Wilford Hall Medical Center	San Antonio, TX					

#### 3) Key Personnel

Starting with the PI, list the names of all individuals functioning as key personnel. Key personnel are defined as individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested by the applicant organization. The PI is the one individual designated by

the applicant organization as responsible for the proper conduct of the study. **Only one individual can be designated as the PI for a study.** The TSNRP does not recognize the use of a *co-Principal Investigator* title. Individuals providing technical services (e.g., transcriptionists) are not considered key personnel.

Principal Investigators previously funded by TSNRP are evaluated on their past compliance with federal, Uniformed Services University of the Health Sciences, and TSNRP requirements, such as timely submission of Institutional Review Board approval documents, progress reports, and publication history.

#### a) Mentoring

A mentoring component is a requirement for *new and junior investigators*, applying for the Novice Investigator, 1-, 2-, 3-Year, and Pilot Project Awards, and *all retired investigators*. Both the mentor and individual being mentored should be listed as key personnel.

New or junior investigators' applications are evaluated on the presence or absence of an experienced mentor as a member of the team, and the support available to the investigator, as outlined in the mentoring plan.

Investigators who are retired from the military are evaluated on the presence or absence of a new or junior military investigator as a member of the research team. The mentoring plan for the new or junior investigator is evaluated for its potential to develop a military nurse researcher, thereby increasing the cadre of military nursing researchers. Details of the mentoring plan must therefore be provided in the personnel section of the Budget Justification (see below).

#### b) Active Duty PIs

In addition to describing the PI's ability to carry out the proposed research (i.e., education, research experience, content expertise, previous work in the proposed area of research, previous experience in other research areas, relevant publications, prior funding, etc.), Active Duty PIs "Time on Station" is considered by reviewers. Therefore, the research team of an Active Duty PI should include a second military nurse at the primary performance site to serve as the site's contact should the PI be away from the site for more than three months (e.g., deployment, permanent change of station, end of time in service, TDY, etc.). Details on Active Duty key personnel must be included in the Budget Justification section (see below).

The stability of the Active Duty PIs research team at the primary performance site is evaluated with consideration to change of duty station, temporary duty, end of time in service, etc.

#### c. Budget and Budget Justification

The budget should include project costs that will be charged to grant funds. Federal employees may not use grant funds for salaries and contributions by Federal employee research team members should be annotated as "without charge," or "WOC," on the budget forms and budget justification section. The budget must be complete, accurate, and reasonable, and within the budget limits for each grant award category (see Part IV.B). When preparing the detailed budget, list only the **direct costs** requested in the application (see Appendix C). Direct costs are those items required to conduct the

research, such as personnel, equipment, and supplies. Applications exceeding the specific award's funding limit will be returned without review.

A narrative justification that is clear and detailed must be provided for all requested major budget items. The budget justification begins on the "Budget for Entire Proposed Project Period – Direct Costs Only" form.

For multiple-year studies, applicants should complete a detailed budget page for each year of the study, and a page for the entire proposed project period. Types of direct costs, by category, are shown below.

#### 1) Personnel Costs

For each individual listed as key personnel, list the percent effort on the project and the individual's base salary on the Detailed Budget pages. The salary requested is calculated by multiplying the individual's base salary by the percent effort on the study.

List the name, role on project, and percent effort for all key project personnel in the Budget Justification, including "Without Charge" personnel. Provide a narrative justification for each person based on his/her role on the project, specific responsibilities for the research, research experience, content expertise, and amount of time proposed to accomplish the research tasks and proposed level of effort. Avoid any duplication of roles and/or responsibilities. For military personnel, include the additional information of their "Time on Station," "Permanent Rotation Date," or "End of Time in Service."

Investigators who have changed their area of research may lack some of the key evaluation aspects listed previously, therefore adequate justification should be provided in the proposal to support the PI's new direction/research area.

For applications requiring mentoring plans, include in the budget justification a clear explanation of the mentor's role, and how the mentoring process will be evaluated. Retired service members must describe how they intend to develop the new investigator's involvement in the conduct of research. A detailed mentoring plan must include the responsibilities of **both** the mentor and the protégé.

#### 2) Consultant Costs

A consultant is an individual hired to give professional advice or services for a fee, and is normally not an employee of the applicant organization. Identify all consultants by name and organizational affiliation, expertise in the specified area, their significant contribution to the success of the study, and describe when and how the consultant's services will be performed.

#### 3) Major Equipment\*

The purchase of equipment for the conduct of research is allowable. Justification for all equipment must be provided in the application.

#### 4) Supplies\*, Materials, Consumables

A general description and estimate of the total cost of expendable equipment and supplies is required. Itemize supplies in separate categories if the total is greater than \$1,000. If animals are to be purchased, state the species and number to be used.

\* Requested computer equipment and software must reflect the needs of the research being conducted. The placement of computer equipment under "Major Equipment" or Supplies, Materials, Consumables," is dependent upon the individual grantee organization's definition of equipment, however, the maximum allowable cost for computer equipment, including software, is \$3,000.

#### 5) Travel Costs

Travel costs may be incurred in the implementation of the research study. List the purpose and destinations for all proposed travel and for each individual. A table may be included for multiple trips. Estimate round-trip airfare (or mileage), hotel, and per diem costs for each trip.

Dissemination of findings is an important component of the research. A maximum of \$1,800 per award may be budgeted for travel to attend a scientific meeting to disseminate research findings. Travel for dissemination typically occurs in the last year of a project.

#### 6) Research-Related Patient Costs

Itemize costs of patient participation in the research study. These costs are limited to expenses specifically associated with the proposed study. Military personnel cannot receive remuneration for participation in research, except for blood draws, which is typically up to \$50 per draw. Consultation with the performance site's legal consultant is recommended during the writing of the proposal to ensure compliance with Department of Defense regulations on remuneration of military personnel.

#### 7) Other Expenses

Itemize other anticipated direct costs, for example, equipment rental, communication costs, transcription costs, advertising costs for study personnel, assistance in manuscript preparation (including editing and proofing), etc. Provide hours and rates for all equipment rental and services. A maximum of \$350 for preparation of dissemination materials is allowed.

8) Indirect Costs—See "Checklist" page.

Examples of corresponding budget documents (Face Page, Detailed Budget for Initial Budget Period, Budget for Entire Proposed Project Period, and Checklist Form Page) have been provided as a reference in Appendix C.

#### d. Biographical Sketch

Biographical sketches should include the person's education, job experience, military assignments, content expertise, research experience, *funding history with the amount of each award*, and other qualifications appropriate to their role on the research team. Evidence of publications emanating from previously funded research should be provided as part of the biographical sketch. PIs who have previously received TSNRP funding are evaluated on their efforts to disseminate the findings of their TSNRP-funded research. The TSNRP strongly advises investigators not to use biographical sketches that have been prepared for other purposes. The biographical sketches will be most effective if tailored to the specific proposal.

#### e. Other Support

Other Support is defined as all financial resources (Federal, non-Federal, commercial, or institutional) available in direct support of an individual's research endeavors. Information on Other Support assists TSNRP in identifying investigators' potential overlap in support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Complete an "Other Support" page for all key personnel.

#### f. Resources

Applicants are advised to focus on those institutional resources that are particularly relevant to the proposed research study. Proposal reviewers want to be assured that investigators have access to all of the material/facilities/services that will be needed to conduct the research study. It is also helpful to include information on conduciveness of the environment to successfully complete the research, access to resources needed to conduct the research study (e.g., material, computers, copiers, medical equipment, library, laboratories, testing centers, space, services, and scholarly environment, etc.), and any related research being conducted by other investigators at the research site. Having on-site colleagues who are interested and involved in studies related to your research area can be a valuable resource.

#### g. Research Plan

PIs are encouraged to use all allowable space to explain their research plan. The text should be formatted according to the guidelines on page 9. Areas for discussion in the Research Plan are shown below.

#### 1) Specific Aims

This section, the foundation on which the rest of the proposal will be built, is one of the most important parts of the proposal. If sufficient time and thought are invested in this first stage of the proposal, the rest should flow smoothly. In addition to listing the broad, long-term objectives (or purposes) and hypotheses for the study's research questions, the Specific Aims section should: 1) be easy to read and logically presented, 2) suggest the relevance of the proposed study to the mission of the TSNRP, 3) refer to the current state of knowledge in the area of study, noting how the proposed study will fill gaps in that body of knowledge, and 4) indicate the expected outcomes of the study and the expected impact of the study findings. A direct relationship between the hypotheses (or research questions), data collected, and analysis should be fully presented.

#### 2) Background and Significance

In the Background and Significance section, the proposal's aims should be well substantiated from previous research. Emphasis in this section is on: citation of specific research literature supporting the significance of the research problem, identification of gaps the proposed research is intended to address, support of the selected methodology, to include a conceptual framework if applicable, instruments/ measurement techniques, or procedures. Citation of, and specific credit for, another author's work is part of the researcher's scientific and scholarly responsibility. Opinion-based citations do not provide adequate support for the proposed research.

Applicants are encouraged to present any supporting statistics or other pertinent information that further demonstrates the importance of the proposed study to the current body of knowledge in the research area, and the mission of the TSNRP. If

there is an expectation that the proposed research will have practical therapeutic applications for clinical nursing, be sure to include such information by indicating the nursing intervention, expected outcome, and reliability and validity of outcome measures. Finally, include any economic impact that the research findings are expected to produce.

#### 3) Preliminary Studies/Progress Report

In this section, highlight preliminary work the research team has done in the proposed area of study to demonstrate that the research team has mastered the technical aspects of the proposed research, including accessing the proposed sample population, pilot testing proposed instruments, etc.

Relevant data from unpublished research should be included in this section. Describe what the data show and why the findings to date are significant to the proposed work. If necessary, selectively include in the appendices related materials from any published work. In writing this section, keep in mind that the objective is to convince the reviewers that the research team is prepared to undertake the proposed study, and that the research team has a competitive advantage over others working in the field. Only research conducted by members of the proposed research team should be reported in this section.

#### 4) Research Design and Methods

This section should follow directly from the Specific Aim statement. Organize this section carefully to ensure that the Research Design addresses each stated Specific Aim. Present the theoretical/conceptual basis of the Research Design before getting into details of Methods. Discuss sample, instrumentation, the data collection procedure, analysis, and human rights protection in enough detail (e.g., methodology, statistics, discussion of controls) to make clear what will be done, how it will be done, and how the data will be interpreted. **Provide a detailed timeline delineating the proposed progression of the study, to include major tasks/milestones and the period within which they will be accomplished** (see Appendix D). Discuss anticipated problems and plans for alternative strategies should these problems arise.

#### 5) Instruments

Samples of all instruments and assessments of their reliability and validity must be submitted with the application. Inclusion of an instrument table with corresponding reliabilities within the methodology section may assist the scientists reviewing the proposal. Use of untested instruments (except in instrumentation proposals and some qualitative research), or failure to include reliability and validity data, diminishes the credibility of the measures.

#### 6) Sample and Site Availability

Sample selection for the proposed study must be realistic, especially for those studies using military populations. Include the parameters employed and the results of a power analysis to justify the sample size for the research questions addressed in the proposal. Support letters demonstrating access to settings and populations are critical to the application. Specific details as to how subjects will be identified and recruited must be included. The site population should be described as well as the number available for sampling.

#### 7) Data Collection Procedure

Every step in the data collection procedure should be fully described so as to be evident to the reviewers what will be done, how it will be done, and by whom.

#### 8) Human and Animal Use Approvals

Research involving either human subjects or animals must be conducted in full compliance with all applicable Federal regulations and Department of Defense (DoD) policies. If the proposed research involves human subjects, the PI should discuss issues related to human subjects protection (e.g., confidentiality, coercion, volunteerism, data safety, monitoring plan, Health Insurance Portability and Accountability Act compliance, etc.). Applicants may want to consult current DoD, Service, and site-specific human subject protection requirements.

Research involving the use of animals must be conducted at a facility accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Documented Institutional Animal Care and Use Committee (IACUC) approval must be provided if the proposal is funded.

Research taking place on DoD installations or using DoD beneficiaries must have the approval of all appropriate Institutional Review Boards (IRB). Academic institutions' human use approval will not be considered a substitute for the appropriate DoD IRB approval at the performance site. Determination of exempt status for research is the responsibility of the local IRB, and cannot be made by the investigator. Although not required at the time of application, the applicant will be responsible for providing documented IRB approval of the research protocol for each performance site if the proposal is funded. As the grantor, the Uniformed Services University of the Health Sciences' IRB also reviews all TSNRP-funded proposals involving human subjects. Funding for approved applicants will not be dispersed without appropriate IRB approvals from each performance site and the Uniformed Services University of the Health Sciences.

The use of vulnerable populations is subject to strict scrutiny by Human Subjects Committees, potentially causing a lengthy and difficult IRB approval process. The use of multiple performance sites may also slow the IRB approval process. In these cases, IRB approval should be sought early in the application process.

Human use consent forms must state the following under the section labeled "Confidentiality": "The Institutional Review Board of [the specified study site], the Uniformed Services University of the Health Sciences, Bethesda, MD, and other Federal agencies who provide oversight for human subject protection may see your records." If applicable, a draft of an Informed Consent document must be included in the application.

A list of references related to human and animal subjects protection is provided in Appendix F.

#### 9) Reference List

All references cited in the text must appear in the reference list. Another author's work must be cited accurately in the text. Use a reference format that includes the titles of the research articles; the use of a publication manual is recommended.

#### 10) Consortium/Contractual Arrangements

This section should include letters of collaboration, and budget plans for each contractual agreement (including PHS 398 budget pages for initial budget period and entire proposed period).

#### 11) Consultants

Letters of support from consultants, and their biographical sketches, are included in this section. Letters of support from consultants should include scope of work (responsibilities), compensation, level of commitment (percent effort), and duration of commitment.

#### h. Checklist

Facilities and Administrative (F&A)/Indirect costs (overhead) information is calculated and completed by the applicant organization. F&A/Indirect costs are those costs incurred for common or joint objectives within the applicant organization in support of various projects. F&A/Indirect costs, therefore, cannot be readily identified with a specific research project or activity of an organization. A number of activities become a part of what makes up the indirect costs of the organization. These may include local telephone service, accounting and legal services, and operation and maintenance of the facilities. Do not list in the detailed budget any item treated by the applicant organization as an F&A/Indirect cost.

F&A/Indirect cost rates differ among the various institutions according to a Federal rate negotiation agreement. Each organization should have an F&A/Indirect cost rate. F&A/Indirect costs are computed by applying the negotiated indirect cost rate to the direct cost project base. The indirect cost rate is itemized by the applicant organization on the Checklist Form Page and should correspond to the information provided on the budget pages and the Face Page of the application.

#### i. Personal Data on Principal Investigator

This form is required and is to be completed by the PI. Place the form at the end of the original application. Do not copy.

#### i. Appendix

Appendices can include material relevant to the application that is not suited for the body of the application, including (but not limited to) measurement/instrument, consent form(s), list of publications, manuscripts accepted for publication, and letters of support. The number of publications and manuscripts accepted for publication should not exceed 5. No page numbering is necessary for an appendix. **One set of appendices should accompany each copy of the proposal**.

#### 1) Letters of Support

Original letters of support from all heads of departments, which might be affected by any aspect of the research, should be included with the application. Relevant letters should demonstrate that investigators have access to the population and the use of facilities needed to conduct the study.

Individuals named as key personnel and consultants should submit letters of support acknowledging participation, including scope of work (responsibilities), compensation, level of commitment (percent effort), and duration of commitment.

#### 2) Instrument Permissions

The use of any instruments not in the public domain requires the author's permission; a letter acknowledging that permission should be included with the application.

#### 3. Research Fellow Awards

This award is to facilitate training in some aspect of research for Masters-prepared Active Duty and Reserve Nurse Corps Officers, or to expand the research skills of *experienced* Active Duty and Reserve Nurse Corps nurse researchers.

#### Requirements

- Funds **may not** be requested for the purchase of equipment or salary for the research fellow. Funds may only be requested for the following categories: Personnel to compensate non-Federal employee mentors, Consultant Costs, Supplies, Travel, and Other Expenses.
- The Fellow must devote at least 20% effort to work on the grant.
- The application must include a letter of support from the mentor, and a letter of support from the Fellow's Commander (if applicable) for the proposed effort.

Applicants for Research Fellow Awards must use a **combination of PHS 398 and PHS 416-1 forms**. Applications for this award should consist of the following forms, ordered in the following fashion:

- Face Page (PHS 398 form);
- Form Page 2 (PHS 416-1 form);
- Table of Contents (PHS 416-1 Form Page 3);
- Scholastic Performance (PHS 416-1 Form Page 4);
- Background (PHS 416-1 Form Page 5):
- Research (PHS 416-1 Form Page 6);
- Biographical Sketch of Research Fellow (PHS 398 Biographical Sketch form);
- Biographical Sketch of Sponsor (PHS 416-1 Form Page 7);
- Facilities and Commitment (PHS 416-1 Form Page 8);
- Detailed Budget for Initial Budget Period (PHS 398 form);
- Budget for Entire Proposed Period of Support (PHS 398 form);
- Checklist Form Page (PHS 398 form);
- Personal Data Form Page (PHS 398 form).

Applicants should use the PHS 416-1 Continuation Page if space beyond what is provided is needed to complete sections of the application.

The identified "Sponsor" should be the individual who will provide the mentoring experience to the fellow.

#### a. PHS 416-1 Form Page 2

1) Applicant's Education

List all degree programs beginning with baccalaureate or other initial professional education and licensure, to include degrees received or expected. Graduate students are evaluated on course work that supports the proposal, and support from the committee chair.

2) Applicant's Training/Employment

List in chronological order all non-degree training, including postdoctoral research training, all employment after college, and military service.

#### 3) Goals for Fellowship Training and Career

Explain training goals under the proposed grant and their relevance to the applicant's career goals. Identify the skills, theories, conceptual approaches, etc., to be learned or enhanced during the award. Describe how the proposed activities, including any research, will contribute to the achievement of these career goals. You may use a continuation page if necessary.

#### 4) Research Proposal

Using only the space provided, present a succinct and accurate description of the proposed work. State the broad, long-term objectives and specific aims of the research proposal, referring to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Do not summarize past accomplishments and avoid the use of the first person.

#### b. PHS 416-1 Form Page 3 (Table of Contents)

The PHS 416-1 Table of Contents form has been modified to reflect TSNRP requirements for the Research Fellow Award. Only applicants for Research Fellow Awards should use this Table of Contents form.

#### a. PHS 416-1 Form Page 4 (Scholastic Performance)

List by institution and year all undergraduate and graduate courses with grades.

#### b. PHS 416-1 Form Page 5 (Background)

Applicants for Graduate Research Awards should complete only items 25a–26 on this page. Applicants for Research Fellow Awards must complete this entire form.

#### 1) Prior and/or Current TSNRP Support

List all prior and current TSNRP support. List attendance at TSNRP educational events (i.e., grant writing workshops). List involvement with completed and current TSNRP-funded research projects.

#### 2) Academic and Professional Honors

List any honors that would reflect upon the applicant's potential for a research career. Include current memberships in professional societies.

#### 3) Application for Concurrent Support

Check the appropriate box. If the applicant has applied or will be applying for other support that would run concurrently with the period covered by this application, include the type, dates, source, and amount.

#### e. PHS 416-1 Form Page 6 (Research)

#### 1) Research Experience

Summarize, in chronological order, the applicant's research experience, including the problems studied and conclusions. Specify which problems were part of a thesis or dissertation. If the applicant has no research experience, list other scientific experience. Do not list academic courses here. Do not exceed one page.

Summarize Masters Thesis or Doctoral Dissertation. Do not exceed one page.

In chronological order, starting with the most recent, list the applicant's entire bibliography, separating abstracts, book chapters, reviews, and research papers. If the list of publications cannot be accommodated within two pages, select only the most pertinent publications. For each publication, give the authors in published sequence, full title, journal, volume number, page numbers, and year of publication. Indicate if another name was previously used. Manuscripts pending publication or in preparation should be included and identified.

#### 2) Training Plan

The Training Plan is the body of the proposal, specifying the allotment of time to activities, and outlining the mentoring plan. This section should be well-formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed in collaboration with the sponsor, but it is to be written by the applicant.

Specify the activities (research, course work, etc.) the applicant will be involved in under the proposed award and the percentage of time to be devoted to each activity. The percentages (including the applicant's outside obligations) must not exceed 100 percent.

The following topics should be addressed in the Training Proposal:

- Background and Career Goals of the fellow.
- Significance to Military Nursing Research.
- Specific Aims of the Training.
- Mentoring Plan:
  - Identify mentor and demonstrate mentor's extensive expertise in the selected area of study.
  - Formal mentoring plan, developed collaboratively with the mentor. This
    plan could include coursework, didactic training, and individualized
    counseling.
- Final Product: description of the final product to be delivered at the conclusion of the award. For example, publication, research proposal ready for submission, funded research award.

Describe the collaborative process between the sponsor and the applicant in the development, review, and editing of the Training Proposal described. Do not include the respective roles in accomplishing the proposed research.

Explain why the sponsor and institution were selected to accomplish the research training goals.

#### d. PHS 416-1 Form Page 7 (Biographical Sketch of Sponsor)

This form is to be completed by the applicant's sponsor. The Biographical Sketch page from the PHS 398 application may be substituted for this form. If the PHS 398 page is substituted, indicate on the Biographical Sketch the total number of publications.

#### e. PHS 416-1 Form Page 8 (Facilities and Commitment)

This form is to be completed by the applicant's sponsor.

#### 4. Graduate Research Awards

Applicants for this award must include all required PHS 398 forms, and four PHS 416-1 pages: Scholastic Performance (Form Page 4), Background (Form Page 5), Biographical Sketch of Sponsor (Form Page 7), Facilities and Commitment (Form Page 8). Refer to the table on page 12. These pages are also provided in Appendix C. The supplemental pages should be added to the PHS 398 application as follows:

- Scholastic Performance page should follow the graduate student's PHS 398 Biographical Sketch page.
- Background page should follow the PHS 398 Scholastic Performance page.
- Facilities and Commitment page should follow the PHS 398 Resource page.

The documents are accessible online through the TSNRP web site <a href="http://www.usuhs.mil/tsnrp/forms/index.html">http://www.usuhs.mil/tsnrp/forms/index.html</a>. Some general instructions are provided below. The PI's name and rank should be listed at the top right corner of the PHS 416-1 forms.

The identified "sponsor" should be the faculty member with substantial oversight for the student's dissertational/thesis work (i.e., the chair of the dissertation/thesis committee). The TSNRP advises graduate students to:

- Inform the committee chair of the desire to apply for TSNRP funding.
- Secure the committee chair's written support of the proposal.
- Obtain assistance from the committee in preparing the proposal.
- Identify the resources needed to complete the study.

Funding in this award category is to assist the graduate student PI in defraying costs in all aspects of the budget *except personnel hired* to assist with data collection, statistical work, etc. Work done on the dissertation is part of the PI's graduate education, therefore it is expected that the PI will perform the work of the study. Transcription costs are permissible and should be listed under "Other Expenses."

#### c. PHS 416-1 Form Page 4 (Scholastic Performance)

List by institution and year all undergraduate and graduate courses with grades.

#### d. PHS 416-1 Form Page 5 (Background)

Applicants for Graduate Research Awards should complete only items 25a–26 on this page. Applicants for Research Fellow Awards must complete this entire form.

#### 1) Prior and/or Current TSNRP Support List all prior and current TSNRP support. List attendance at TSNRP educational events (i.e., grant writing workshops). List involvement with completed and current TSNRP-funded research projects.

### 2) Academic and Professional Honors

List any honors that would reflect upon the applicant's potential for a research career. Include current memberships in professional societies.

#### 3) Application for Concurrent Support

Check the appropriate box. If the applicant has applied or will be applying for other support that would run concurrently with the period covered by this application, include the type, dates, source, and amount.

#### c. PHS 416-1 Form Page 7 (Biographical Sketch of Sponsor)

This form is to be completed by the applicant's sponsor. The Biographical Sketch page from the PHS 398 application may be substituted for this form. If the PHS 398 page is substituted, indicate on the Biographical Sketch the total number of publications.

#### d. PHS 416-1 Form Page 8 (Facilities and Commitment)

This form is to be completed by the applicant's sponsor.

#### f. Letter of Support

A letter from the student's thesis or dissertation committee chair must be included in the application, and must include statements that the proposal has been approved and/or defended, and that the student has met the school's requirements for thesis or dissertation proposal defense.

#### 5. Fast Track Awards

This award is to assist **experienced** Active Duty nurse researchers in facilitating rapid implementation of short-term research of emerging **service-specific** questions or concerns. Applicants for Fast Track Awards must complete all required PHS 398 forms. Applicants should follow the instructions for completion of the PHS 398 forms, with the exception of guidelines for preparing the Abstract and Research Plan. There are specific requirements for these components of the application.

#### a. Abstract

The abstract is the "Description" section of the PHS 398 Form Page 2, "Description, Performance Sites, and Key Personnel." The abstract should be a brief, stand-alone description of the project, of fewer than 250 words, including a statement of the aims/objectives of the study, hypotheses or research questions, theoretical framework (if applicable), research design, sample, data collection methods, and plan for statistical analysis.

#### b. Research Plan

The research plan should not exceed 10 pages. Listed below are the topics that should be addressed in the Research Plan. Guidelines are provided for each topic. The PI should address only topics applicable to the proposed research.

#### 1) Purpose/Objectives/Specific Aims

List and discuss the purpose/objectives/specific aims of the study.

#### 2) Hypotheses/Research Questions

State the specific hypotheses or research questions to be tested.

#### 3) Significance

State concisely the importance and health relevance of the research, by relating the specific aims to the broad, long-term objectives. State the practical application(s).

#### 4) Military Relevance

With regard to military needs and mission requirements (e.g., Readiness, TriCare, Building Healthy Communities), this section should provide a brief and succinct military justification for the research.

#### 5) Background/Review of Literature

Briefly describe the background leading to the present study. Critically evaluate existing knowledge and identify the gaps that the project is intended to fill.

#### 6) Preliminary Studies/Progress Report

Highlight preliminary work the research team has done in the proposed area of study. Relevant data from unpublished research should be included in this section. Describe what the data show and why the findings to date are significant to the proposed work. If necessary, selectively include in the appendices related materials from any published work.

#### 7) Research Design, Methods, and Randomization Process

Describe how the research is designed to answer the hypotheses/research questions, and how the research is to be conducted. Be very specific as to who will perform what procedure, how each procedure will be performed, and the sequence of the procedure in the overall study. Be sure to indicate whether or not the specific procedures are "Standard of Care" (i.e., would be done even if the subject were not included in the study). Describe the study arms, the randomization points (i.e., at study entry or later), and the criteria for patient stratification.

#### 8) Data Collection and Measurement

Describe data to be collected, data collection procedures, any required data collection forms, how the data obtained will be stored, and procedures for safeguarding confidential subject information. Define what measurements (operational definitions, independent and dependent variables) the study will evaluate to answer the research question. Describe the accuracy and precision of equipment that will be used to measure the outcome variables. Include information on the reliability and validity of surveys or questionnaires; include a copy of the survey/questionnaire.

9) Target Sample, Sample Size, and Inclusion/Exclusion Criteria
Describe the characteristics of the target population, including their anticipated age range, and health status. Include a sample size estimation/power analysis. State the anticipated effect size, and alpha level. Indicate the number of subjects to be enrolled, and the distribution of subjects among data collection sites. List inclusion/exclusion criteria and rationale.

## 10) Human Subject Protection, Recruitment, Benefits, Risks, and Risk/Benefit Assessment

All subjects should be treated in compliance with human subjects protection regulations and applicable DoD, Food and Drug Administration, and Health and Human Services guidelines. Describe how subjects will be recruited and the consent procedure; include the circumstances under which consent will be sought and obtained. Describe any benefit to the subject or others that may reasonably be expected from the research. Describe the potential risks or discomforts (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Describe the potential benefits to subjects or to others that may reasonably be

expected from the research. Discuss why the risks to the subjects are reasonable in relationship to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

#### 11) Vertebrate Animals

Research involving the use of animals must be conducted at a facility accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).

#### 12) Data Analysis

Describe the data analysis strategy, including the statistical tests or procedures to be used with each variable or group of variables, and/or each hypothesis/research question. Identify and discuss any assumptions made (variability of instrumentation, analytical detectable limits, etc.). Identify who will be responsible for final data analysis.

#### 13) Timeline

Provide a detailed timeline delineating the proposed progression of the study, to include major tasks/milestones and the period within which they will be accomplished. Identify any distinct phase points (subject accrual, treatment phase, follow-up, data analysis, etc.). A sample timeline is provided in Appendix D.

#### 14) Reference List

Cite referenced literature.

There is a customized PHS 398 Table of Contents form for the Fast Track Award (see Appendix D), including the Research Plan's required topics. This document is accessible online through the TSNRP web site <a href="http://www.usuhs.mil/tsnrp/forms/index.html">http://www.usuhs.mil/tsnrp/forms/index.html</a>.

## VIII. PROPOSAL EVALUATION

#### A. REVIEW PROCESS

The review process for applications varies according to the award type. Proposals for Novice Investigator, 1-, 2-, 3-Year, Pilot Project, Graduate Research, and Research Fellow Awards undergo a two-tiered review process: scientific merit review and programmatic review. Applications for Fast Track Awards undergo a one-tiered review process independent from the review of applications for other award types. Outcomes from all reviews guide funding decisions made by the TSNRP's Executive Board of Directors. Throughout the review and decision process, confidentiality and conflict-of-interest measures are enforced.

## 1. Review of Novice Investigator, 1-, 2-, 3-Year, Pilot Project, and Research Fellow Awards

The scientific merit review is a *criterion*-based process by which individual proposals are evaluated and scored. The review scores proposals on a scale of 1–5 (in intervals of 0.1); the scoring scale is as follows:

Rating Range	<b>Adjective</b>
1.0-1.5	Outstanding
1.6-2.0	Excellent
2.1–2.5	Very Good
2.6-3.5	Good
3.6-5.0	Fair

#### a. Scientific Merit Review

During scientific merit review, each proposal is evaluated for scientific and technical merit, without regard for the other proposals under consideration.

A Scientific Review Panel (SRP), consisting of a panel chair and civilian and military nurse scientists, is responsible for reviewing, discussing, and scoring the scientific merit of proposals. Panel members are selected from the nursing and healthcare communities based on their research, work experience, and publication history. Two reviewers with expertise in the subject area are selected to evaluate each proposal and provide written evaluations. During the scientific merit review, the reviewers present the proposal, their reviews, and scores to the entire SRP. The panel discusses the proposal; each panel member then scores the proposal individually. The final score is a mean of all panel members' scores.

Military nurse scientists participate in the scientific merit review, but do not score the proposals. Military nurse scientists from one or more services are selected to evaluate proposals for military relevance and feasibility of the research from a military perspective. In reviewing a proposal, the military nurse scientist considers the potential contribution of the proposed research to military nursing, the importance of the research problem to military healthcare, the feasibility of a military research team conducting the proposed research, including the "Time On Station" of military research team members, and the feasibility of accessing and recruiting the proposed sample. The military nurse scientist presents his/her findings to the SRP prior to the scoring of the proposal. During the panel discussion, the military nurse scientists advise the SRP on military-specific concerns.

## 1) Criteria Used in Evaluating Novice Investigators, 1-, 2-, 3-Year, and Pilot Project Awards

- Original, innovative, and applicable to military healthcare:
  - Reviewers assess originality of the nursing research problem, including whether or not new concepts, approaches, or methods are used.
  - Reviewers assess the innovation in translation or applicability of previous findings to answer military nursing or healthcare problems.
- Hypothesis/research question, rationale, and research strategy:
  - Reviewers assess strengths and weaknesses of the study's design and determine whether the research will likely reach its stated goal.
  - Reviewers assess appropriateness, feasibility, and adequacy of the approach, research design, and methodology.
- Preliminary data (if applicable).
- Scientific relevance and potential contributions:
  - Reviewers evaluate the potential contribution to nursing and the importance of the research problem addressed. Reviewers also address strengths and weaknesses of these important criteria.
- Reliability and validity of data collection instruments.
- Qualifications of PI and research team:
  - Reviewers evaluate the training and track record of all investigators playing a key role in the proposal. Reviewers note the following for each key individual: name, degree(s), title, field of training or experience, publication record, ability to conduct the research, and whether or not the investigator is a student in an academic program. They also note any missing expertise required for the research.
- Availability of appropriate resources and an environment conducive to successful completion of the project.
  - Reviewers assess the intellectual and physical environment provided by the institution, to include: equipment, space, computers, library, germane facilities, ongoing research, opportunities for interaction with other knowledgeable colleagues, and military environment feasibility. The reviewers list apparent strengths and weaknesses in the environment.
- Soundness of the proposed budget:
  - Reviewers evaluate completeness and accuracy of the budget.
  - Reviewers evaluate the reasonableness of requested personnel costs, equipment, and supplies.
  - Reviewers may recommend budget modifications.
- Publications:
  - Reviewers assess the investigator(s)' peer-reviewed publication history.

#### 2) Criteria Used in Evaluating Research Fellow Awards

- Candidate qualifications:
  - Reviewers assess the quality of the candidate's academic record.
- Mentor qualifications:
  - Reviewers assess the appropriateness of the mentor's qualifications in the topic of study.
  - Reviewers assess the quality and extent of mentor's proposed role in providing guidance and advice to the candidate.
  - Reviewers assess the previous experience in fostering the development of researchers.
  - Reviewers assess the history of research, productivity, and support.
- Mentoring Plan:
  - Reviewers assess the likelihood that the career development plan will contribute substantially to the professional development of the candidate.
  - Reviewers assess the appropriateness of the content and duration of the proposed training.
  - Reviewers assess the quality of the proposed training.
- Environment:
  - Reviewers assess the support of the command for release time for the training.
  - Reviewers assess the adequacy of facilities.
  - Reviewers assess the availability of appropriate educational opportunities.
  - Reviewers assess the quality and relevance of the environment for scientific and professional development of the candidate.
- Budget:
  - Reviewers assess the justification of the requested budget in relation to career development goals and research aims.

#### b. Programmatic Review

The TSNRP Advisory Council, consisting of one Active Duty and one Reserve member from each service, conducts the programmatic review. Programmatic review is both a *criterion*- and *comparison*-based process in which individual proposals are evaluated for relevance to the TSNRP portfolio with regard to the other proposals under consideration. The review scores proposals on a scale of 1–5 (in intervals of 0.1); the scoring scale is as follows:

Rating Range	<b>Adjective</b>
1.0-1.5	Outstanding
1.6-2.0	Excellent
2.1–2.5	Very Good
2.6–3.5	Good
3.6-5.0	Fair

Council members review portions of the proposals and the outcomes of the scientific merit review. One member is selected to provide a written evaluation for each proposal; a second member also scores the proposal. During the programmatic review, the primary reviewer presents the proposal, the review, and the score to the entire panel; the secondary reviewer presents the proposal's score and justification. The entire council discusses the proposal and then agrees on a final score.

1) Criteria Used in Evaluating Novice Investigator, 1-, 2-, 3-Year, and Pilot Project Awards

#### Reviewers assess:

- Military relevance.
- Military uniqueness.
- Relevance to the TSNRP portfolio; proposals are compared on this criterion.
- Strengths and stability of the investigative team.
- Potential benefit of the proposed research relative to the proposed budget.
- The investigators' military experience, and both military and civilian education
- a) Criteria applicable only to previously funded PI
  - Past performance history: Reviewers evaluate the PI's compliance with the terms and conditions of previous award(s), and compliance with reporting requirements.
  - Dissemination efforts: Reviews evaluate the PI's efforts at disseminating TSNRP-funded research findings, including papers and poster presentations. TSNRP expects timely publication of findings in peer-reviewed journals.
- 2) Criteria Used in Evaluating Research Fellow Awards
  - Reviewers assess the candidate's commitment to military nursing research.
  - Significance to military nursing research: Reviewers assess the consistency of the career development plan with the candidate's career goals and prior research experience.
    - Retain-ability.
  - Environment: Reviewers assess the support of the command for release time for this training.

Based on programmatic review, the Advisory Council makes recommendations for funding to the Executive Board of Directors.

#### c. Funding Decisions

Final determinations for funding are made by the Executive Board of Directors comprising the Chief of the Army Nurse Corps and the Directors of the Navy and Air Force Nurse Corps. Funding decisions are based upon the mission and focus areas of the TSNRP, outcomes of the scientific merit and programmatic reviews, and recommendations of the Advisory Council. Applicants for the 1-, 2-, 3-Year, Pilot Project, Graduate Research, and Research Fellow Awards should expect to be notified of their proposals' funding status in April 2004.

As the funding decisions are separate from the scientific review process, decisions may not be appealed.

#### 2. Review of Graduate Research Awards

#### a. Programmatic Review

- Scientific merit.
- Feasibility and scope of study.
- Military Relevance: timeliness of the topic.

- In determining the graduate student's ability to carry out the proposed research, the reviewers also consider:
  - The student's research education to date.
  - Expected course work.
  - The availability of guidance by the student's sponsor.
  - Support letter from the dissertation or thesis committee chair.

#### b. Funding Decision

Final determinations for funding are made by the Executive Board of Directors, based upon TSNRP's mission and focus areas and the outcomes and recommendations of the programmatic review by the Advisory Council.

As the funding decisions are separate from the scientific review process, decisions may not be appealed.

#### 3. Review of Fast Track Awards

#### a. Programmatic Review

- Scientific merit.
- Feasibility and scope of study.
- Military Relevance: timeliness of the topic.

#### b. Funding Decision

Final determinations for funding are made by the Executive Board of Directors, based upon TSNRP's mission and focus areas and the outcomes and recommendations of the programmatic review by the Advisory Council.

As the funding decisions are separate from the scientific review process, decisions may not be appealed.

## IX. ADDITIONAL INFORMATION

#### A. PROPOSAL TOPIC CONSULTATION

Applicants may contact service-specific Research Consultants/Specialty Leaders to discuss proposal topics or the development of a proposal topic, to determine if a proposed topic would be of interest to the military services. Names and contact information of the Research Consultants/Specialty Leaders are listed in Appendix F.

#### B. CHANGES IN ADDRESS OR STATUS OF PRINCIPAL INVESTIGATOR

To keep records up-to-date, the PI must inform the TSNRP office of any changes in mailing address, phone number, fax number, e-mail address, military assignment, rank. Not reporting a change in address could delay the PI's receipt of funding decision notification. Updated information can be submitted online at <a href="http://www.usuhs.mil/tsnrp/updatecontact.html">http://www.usuhs.mil/tsnrp/updatecontact.html</a>, or by mail to the following address:

CDR Patricia W. Kelley, NC, USN Director TriService Nursing Research Program Uniformed Services University of the Health Sciences 4301 Jones Bridge Road Bethesda, MD 20814-4799

The PI should also notify the applicant organization managing the grant of any of the aforementioned changes.

#### C. CHANGES IN KEY PERSONNEL, WORK EFFORT, OR JOB RESPONSIBILITIES

The PI is responsible for knowing the percent effort and job responsibilities of all personnel associated with the research. Any changes after funding in percent effort or job responsibilities, as well as the addition or removal of key personnel, require approval from TSNRP prior to the change.

#### D. CONTRACT VENDOR REGISTRY

Effective 1 June 1998, all applicant organizations (i.e., grantees) doing business with the DoD must be registered in the Central Contractor Registration (CCR). Through this DoD registry, the applicant organization receives a Trading Partner Identification Number (TPIN). The CCR is designed to be a single point of registration for all DoD grantees.

Any applicant organization currently representing a funded TSNRP grant should already be registered in the CCR. If this is the first time that an applicant organization is receiving DoD funding, then it may be necessary for the applicant organization to register. **The PI should ensure** that the applicant organization representing the proposal is registered in the CCR. The CCR is accessible online through <a href="http://www.ccr.gov">http://www.ccr.gov</a>.

Prior to executing the grant agreement, an applicant organization must have a TPIN. If an applicant organization is uncertain if they are registered or wants information on how to register, the signing official may call the TSNRP office.

#### E. ETHICAL ISSUES

Nurse investigators must consider many areas such as human subjects protection, scientific integrity, stewardship of funds, implications of new findings, and authorship when thinking of applying for a grant. Careful attention must be given to acknowledging and accurately citing work done by others, including abstracted and annotated writings. These are not always straightforward issues and require careful consideration.

Another matter of concern is the issue of "fronted" studies. "Fronted" studies are projects prepared by a non-eligible investigator and submitted under an eligible applicant's name in an attempt to obtain funding for research that would normally not be funded by the granting agency. Such submissions are inappropriate, and once identified will not be funded.

Once proposals are approved for funding, they are closely monitored throughout the award period. Lack of investigational progress, evidence of misuse of funds, or other scientific misconduct are subject to review and can result in serious repercussions for the investigator and the applicant organization.

## **APPENDIX A**

### TSNRP AWARD HISTORY

Year	Total Appropriated (Millions)	Proposals Received	Proposals Funded		
1992	1 M	66	8 (12%)		
1993	2 M	58	22 (38%)		
1994	3 M	40	24 (60%)		
1995	5 M	79	23 (29%)		
1996	5 M	61	29 (48%)		
1997	5 M	53	30 (57%)		
1998	5 M	63	27 (43%)		
1999	5 M	44	19 (43%)		
2000	6 M	36	19 (53%)		
2001	4 M	35	11 (31%)		
2002	6 M	48	18 (38%)		
2003	6 M	33	15 (45%)		

## **APPENDIX B**

#### NONPROFIT ORGANIZATIONS

Principal Investigators should directly contact non-profit organizations for their indirect cost rate and services provided.

Henry M. Jackson Foundation for the Advancement of Military Medicine 1401 Rockville Pike, Suite 600 Rockville, MD 20852-2007

Phone: 301-424-0800

Office of Sponsored Programs

http://www.hjf.org

Applicants choosing the Henry M. Jackson Foundation must obtain Guest Scientist status from the Foundation.

The Geneva Foundation
3315 South 23<sup>rd</sup> Street, Suite 209
Tacoma, WA 98405
Phone: 253-383-1398
Attn: Donna T. Luinstra
Executive Director
http://www.thegenevafoundation.org

T.R.U.E. Research Foundation 8610 N. New Braunfels Suite 705 San Antonio, TX 78217-6359 Phone: 210-829-1239

Toll Free: 888-329-1239
Attn: Terri Nakamura
Research Director

http://www.trueresearch.org/

### **APPENDIX C**

### **FORMS**

### **TSNRP FORMS**

- Letter of Intent to Submit Application
- Grant Application Cover Sheet
- Relevance to Military Nursing

### PHS 398 FORMS

#### General Use

- PHS 398 Face Page
- PHS 398 Detailed Budget Page for Initial Budget Period
- PHS 398 Budget Page for Entire Proposed Project Budget Period
- PHS 398 Checklist (usually completed by the applicant organization)

### Fast Track Awards

• PHS 398 Table of Contents – Modified

### **PHS 416-1 Forms**

### Graduate Research Awards

- PHS 416-1 Pages
  - **□** Scholastic Performance (Form Page 4)
  - □ Background (Form Page 5)
  - □ Biographical Sketch of Sponsor (Form Page 7)
  - □ Facilities and Commitment (Form Page 8)

### Research Fellow Awards

- PHS 416-1 Pages
  - □ Form Page 2
  - □ Table of Contents (Form Page 3)
  - Scholastic Performance (Form Page 4)
  - Background (Form Page 5)
  - □ Research (Form Page 6)
  - □ Biographical Sketch of Sponsor (Form Page 7)
  - □ Facilities and Commitment (Form Page 8)

# **TSNRP Forms**

Letter of Intent to Submit Application

**Grant Application Cover Sheet** 

Relevance to Military Nursing

I intend to submit a grant application in response to the TriService Nursing Research Program <b>FY 2004-A Call for Proposals</b> .
First Name:
Last Name:
Rank:
Service Branch:
Mailing Address:
E-mail Address:
Telephone:
Fax:
Proposal's Working Title:
Research Objectives:
Study Population/Sample:

Study Design:
Analysis Plan:
Performance Site(s):
Pagagrah Taam (if known) and Palag
Research Team (if known) and Roles:
Гуре of Award:
Novice Investigator
1 year study 2 year study
3 year study Pilot Project study
Graduate Research
Research Fellow Fast Track
Applicant Organization:

# TRISERVICE NURSING RESEARCH PROGRAM GRANT APPLICATION COVER SHEET

(Please type or print)

<b>Principal Investigator</b>	:			Rank:
•	(Las	t, First, Middle	e initial)	
Branch of Service and	Component:			
ARMY	ACTIVE	RESERVE	GUAR	D RETIRED
NAVY	ACTIVE	RESERVE		RETIRED
AIR FORCE	_ ACTIVE	RESERVE		
HOME ADDRESS				
Phone: E-mail:	FAX:			
E-man:				
MILITARY ASSIGNMEN	T			
Position Title:				
<b>Duty Station /Unit:</b>				
Address:				
DSN:				
Commercial:				
FAX:				
E-mail:				
CIVILIAN POSITION (if	annlicable)•			
Position Title:	аррисион.			
Address:				
Audress:				
	77.47			
Phone:	FAX:			
E-mail:				
<b>Preferred Contact Ad</b>	dress/Phone/FAX	X/E-mail (chec	k one): Hom	e MilitaryCivilian
Nursing Specialty (che	eck all that apply)	•		
ICU Med-Surg	110/		GYN Psy	ch Nurs. Admin.
Community Health				
Category of award for	this application	(check one):		
Novice Investigator	Award		Pilot Project Aw	vard
1-Year	1 1 W U1 U		Graduate Resear	
- 1-1 ear 2-Year			Research Fellow	
3-Year			Fast Track Awar	ıu

•	e main research priority that is investigated in this propo 4-A Call for Proposals Part III "Research Priorities"):	sai	
Research P	riority Area:		
Identify 2-3	8 key words relating to the proposal:		
Active ARMY NAVY AIR FOR	llation (check all that apply):  Duty Reserve Beneficiaries  ARMY Spouses Children  RCE AIR FORCE Retiree GUARD Elderly  ication a revision of a previously submitted application?  year of application and title of project:	YesNo	)
Year	Year of application and title of project.  Title		
•	pplied as a Principal Investigator for TSNRP support in year of application, title of project, proposal number (e.g., Nas funded:	_	
YEAR	TITLE	Number	(Yes/No)
	Attach list if additional space is needed		
related to e Title, Type Location (C Policy Pape	sly funded by TSNRP must report, as attached pages, diach of their TSNRP-funded studies. For each presentation (e.g. poster/podium/other), Author Name, Venue (e.g. Confeity, State/Country). For each publication report: Type (e.g. Jr), Author Line, Publication Title, Source Title, and Date. Prapplicable), using APA format. Provide publication status (e.g. State Prapplicable).	n report: Prese erence Name), ournal, News rovide full jou	entation Date, letter, rnal
grant writi	eceived grant writing support from attendance at a TSN ng workshop, or the on-line course "Research and Propo RAPPS)"? Yes No	-	
Date	METHOD OF LEARNING L	ocation (if wo	rkshop)
How and w	hen did you first learn of TSNRP funding opportunities?	,	

PI Last Name, First Name & Rank

### TRISERVICE NURSING RESEARCH PROGRAM

### RELEVANCE TO MILITARY NURSING

**DIRECTIONS:** In the space provided below, please state the relevance of the proposed research to military nursing and how the research will expand the body of military scientific knowledge or military nursing practice.

DO NOT EXCEED THIS SPACE.							

# **PHS 398 Sample Pages**

**Profile:** 

Active Duty PI 2-year study Non-Profit Organization

Forms:

Face Page
Detailed Budget for Initial Budget Period (Year 1)
Detailed Budget for Year 2)
Budget for Entire Proposed Project Period
Checklist

LEAVE BLANK—FOR PHS USE ONLY. Department of Health and Human Services **Public Health Services** Type Activity Number Review Group Formerly Grant Application Follow instructions carefully. Council/Board (Month, Year) Date Received Do not exceed 56-character length restrictions, including spaces. 1. TITLE OF PROJECT An Intervention for Nurses with Bad Exercise Behaviors 2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES (If "Yes," state number and title) Title: TriService Nursing Research Program Number: N/A 3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ☐ Yes New Investigator No 3a. NAME (Last, first, middle) 3b. DEGREE(S) Murphy, Patricia RN, MN PhD 3c. POSITION TITLE 3d. MAILING ADDRESS (Street, city, state, zip code) Nurse Researcher 3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT 124 Challenger Street **Nursing Research Department** America City, MD 12345-0000 3f. MAJOR SUBDIVISION Nursing 3g. TELEPHONE AND FAX (Area code, number and extension) E-MAIL ADDRESS: TEL: (123) 456-7890 Ipaul@bestevernetwork.com FAX: (123) 098-7654 4. HUMAN SUBJECTS 4a. Research Exempt 5. VERTEBRATE ANIMALS ☐ No ☐ Yes RESEARCH If "Yes." Exemption No. ☐ No 5a. If "Yes," IACUC approval Date 4b. Human Subjects 5b. Animal welfare assurance no 4c. NIH-defined Phase III Assurance No. ✓ Yes Clinical Trial ☐ No ☐ Yes 6. DATES OF PROPOSED PERIOD OF 7. COSTS REQUESTED FOR INITIAL 8. COSTS REQUESTED FOR PROPOSED SUPPORT (month, day, year—MM/DD/YY) **BUDGET PERIOD** PERIOD OF SUPPORT Through 7a. Direct Costs (\$) 7b. Total Costs (\$) 8a. Direct Costs (\$) 8b. Total Costs (\$) From 6/1/04 5/31/06 \$130,976 \$245.353 \$245.353 \$269.889 9. APPLICANT ORGANIZATION 10. TYPE OF ORGANIZATION Acme Foundation State Public: → | Federal Local Private: → Private Nonprofit Address 9876 Beausoleil Street, Suite 1 For-profit: → ☐ General ☐ Small Business America City, MD 12346 Woman-owned Socially and Economically Disadvantaged 11. ENTITY IDENTIFICATION NUMBER 12-3456789 DUNS NO. (if available) Congressional District 6 Institutional Profile File Number (if known) 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE 13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Kay Ginn Name Kay Ginn Title Director Title Director Address Acme Foundation Address Acme Foundation 9876 Beausoleil Street, Suite 1 9876 Beausoleil Street, Suite 1 America City, MD 12346 America City, MD 12346 Tel (123) 567-8904 FAX (123) 567-8901 Tel (123) 567-8904 FAX (123) 567-8901 kayginn@acmefoundation.org kayginn@acmefoundation.org E-Mail E-Mail 14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the SIGNATURE OF PI/PD NAMED IN 3a. DATE statements herein are true, complete and accurate to the best of my knowledge. I am (In ink. "Per" signature not acceptable.) aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. 15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the SIGNATURE OF OFFICIAL NAMED IN 13. DATE statements herein are true, complete and accurate to the best of my knowledge, and (In ink. "Per" signature not acceptable.) accept the obligation to comply with Public Health Services terms and conditions if a grant

is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SBIR/STTR Only: FIXED FEE REQUESTED					
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)					
COSTS	FACILITIES AND ADMINISTRATIVE COSTS	(			
CONSORTIUM/CONTRACTUAL	DIRECT COSTS	(			
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD					

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY  FROM 6/1/2005								GH (31/2006
PERSONNEL (Applicant organization	n only)		%		DOLLAR AM	OUNT REQUES	STED (	(omit cents)
NAME	ROLE ON PROJECT	TYPE APPT. (months)	EFFORT ON PROJ.	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	3	TOTAL
Patricia Murphy	Principal Investigator	12	5.0	79,308	WOC	WO	С	WOC
Julie Roberts	Co-I	12	5.0	64,689	WOC	WO	С	WOC
Deborah Perkins	Project Director	12	100.0	64,500	64,500	16,12	25	80,625
To be hired	RA	12	50.0	31,000	15,500	3,87	75	19,375
S.Tatsisme	Statistician	2	25.0	61,000	2,542	63	35	3,177
	SUBTOTALS	<b>.</b> —		<b>→</b>	82,542	20,63	35	103,177
CONSULTANT COSTS  Dr. Ima Expert – 1.25 day  EQUIPMENT (Itemize)	on-site consul	tation				6,00	00	6,000
-								0
SUPPLIES (Itemize by category) Office Supplies \$100/mon	ı x 12 mon \$1	,200						
TDAVEL								1,200
TRAVEL Principal Investigator trave	el to National C	Conferenc	e (vear 2)	•		1,50	00	1,500
	INPATIENT		() () () ()	<u>'</u>		.,		0
	OUTPATIENT							0
ALTERATIONS AND RENOVATION	IS (Itemize by cate	gory)						
OTHER EVERNOES (there're have	4	N	lone					0
OTHER EXPENSES (Itemize by ca Duplication Costs \$1,200								
Presentation preparation \$250								
Communication Costs \$720								
Manuscript preparation \$330							2,500	
SUBTO	TAL DIRECT CO	OSTS FOR	INITIAL B	UDGET PER	IOD		<b>\$</b> 1	14,377
CONSORTIUM/CONTRACTUAL	DIRECT COSTS							0
COSTS FACILITIES AND ADMINISTRATIVE COSTS							0	
TOTAL DIRECT COSTS FO	R INITIAL BUD	GET PER	IOD (Item 7	7a, Face Page)		<b>&gt;</b>	<b>\$</b> 1	14,377
SBIR/STTR Only: FIXED FEE REQUESTED								

### **BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD DIRECT COSTS ONLY**

BUDGET CA	ATEGORY	INITIAL BUDGET PERIOD	ADDITIONAL YEARS OF SUPPORT REQUESTED					
TOTALS		(from Form Page 4)	2nd	3rd	4th	5th		
PERSONNEL: Salary and fringe benefits. Applicant organization only.		103,177	103,177	0	0	(		
CONSULTANT O	COSTS	4,000	6,000	0	0	(		
EQUIPMENT		18,049	0	0	0	C		
SUPPLIES		1,550	1,200	0	0	C		
TRAVEL		1,200	1,500	0	0	0		
CARE	INPATIENT	0	0	0	0	0		
	OUTPATIENT	0	0	0	0	0		
ALTERATIONS AND RENOVATIONS		0	0	0	0	0		
OTHER EXPENSES		3,000	2,500	0	0	0		
SUBTOTAL DIRI	ECT COSTS	130,976	114,377	0	0	0		
CONSORTIUM/	DIRECT	0	0	0	0	0		
CONTRACTUAL COSTS	F&A	0	0	0	0	0		
TOTAL DIRECT COSTS		130,976	114,377	0	0	0		
TOTAL DIREC	CT COSTS FO	R ENTIRE PROPOSED P	PROJECT PERIOD (II	em 8a, Face Page)	\$ 2	245,353		
SBIR/STTR O Fixed Fee Red								

(Add Total Fixed Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

\$

• Pr	rincipal Investigator/Progra	am Director (Las	t, first, middle):	Murphy,	Patricia Col	
CHECKLIST						
TYPE OF APPLICATION (Check ali	that apply.)					
NEW application. (This applic	cation is being submitted to	o the PHS for the	e first time.)			
	R Phase II: SBIR Phase I		,		SBIR Fa	st Track
	TR Phase II: STTR Phase	_			- =	ast Track
REVISION of application numb	oor:	_				
(This application replaces a price		ew, competing c	ontinuation, or	supplemental ap	plication.)	
COMPETING CONTINUATIO	N of grant number:				S AND PATENTS continuation appl. and	Phase II only)
(This application is to extend a		current project p	eriod.)	_ No		eviously reported
SUPPLEMENT to grant numb	er.			Yes. If "		t previously reported
(This application is for addition		currently funded	grant.)	165.	Tes, [110]	previously reported
CHANCE of principal investiga	-t/					
CHANGE of principal investigations  Name of former principal investigations  N	· -					
FOREIGN application or signif     PROGRAM INCOME (See inst						
All applications must indicate wheth	ner program income is ant		ne period(s) for	which grant sup	port is request. If prog	gram income
is anticipated, use the format below	T	. ,				
N/A	Anticipa	ated Amount	0	N/A	Source(s)	
IN/A			U	IN/A		
2. ASSURANCES/CERTIFICATIO			•Dobarmont a	nd Suppopoion:	Drug- Free Workplace	(appliable to now
The following assurances/certificati signature of the Official Signing for Page of the application. Descriptior certifications are provided in Sectio where applicable, provide an explaid Human Subjects; Research Using Research on Transplantation of Hi	Applicant Organization on as of individual assurances in III. If unable to certify con nation and place it after the Human Pluripotent Stem	n the Face s/ ompliance, is page. Cells•	[Type 1] or rev Delinquency of HHS 441 or H HHS 690); •Se Discrimination Human Gene	vised [Type 1] ap, on Federal Debt; HS 690); •Handid ex Discrimination (Form HHS 680 Transfer Researd	plications only); *Lobb •Research Misconduct capped Individuals (Form HHS 639-A or or HHS 690); •Recom ch; •Financial Conflict NLY: Certification of R	ying; •Non- ;; •Civil Rights (Form rm HHS 641 or HHS 690); •Age binant DNA and of Interest (except
Minority Inclusion Policy •Inclusion	of Children Policy• Verteb	rate Animals•	Participation.	,		
3. FACILITIES AND ADMINSTRA	TIVE COSTS (F&A)/ INDI	RECT COSTS.	See specific ins	structions.		
DHHS Agreement dated:				No Faciliti	es And Administrative	Costs Requested.
DHHS Agreement being negot	iated with			Re	gional Office.	
No DHHS Agreement, but rate	established with US	UHS			Date 1/2	9/02
CALCULATION* (The entire grant a	application, including the C			d provided to pe		ential information.
Supplying the following information of	•	r for-profit organ 130,976	,	ed 10	0/ - 59 A	13,098
a. Initial budget period:	Amount of base \$	114,377	x Rate applie		% = F&A costs \$	11,438
b. 02 year	Amount of base \$	114,577	x Rate applie		% = F&A costs \$	11,430
c. 03 year	Amount of base \$		x Rate applie		% = F&A costs \$	
d. 04 year	Amount of base \$		x Rate applie		% = F&A costs \$	
e. 05 year	Amount of base \$		x Rate applie		% = F&A costs \$	24.526
*Objects and an arranged to the Control of the Cont					TOTAL F&A Costs \$	24,536
*Check appropriate box(es):		C 14 4 1 11 4		$\square$	ou	
Salary and wages base		fied total direct o	cost dase		Other base (Explain)	
Off-site, other special rate, or		ed ( <i>Explain</i> )				
Explanation (Attach separate sheet,	п necessary.):					
4. SMOKE-FREE WORKPLACE	Yes No (	The response to	this question h	nas no impact on	the review or funding	of this application.)

PHS 398 Table of Content for Fast Track A	wards



# FAST TRACK AWARD RESEARCH GRANT TABLE OF CONTENTS

		Pag	e Numbers
	Page		1
Desc	cription, Performance Sites, and Personnel	2-	
Tabl	e of Contents		
Deta	iled Budget for Initial Budget Period (or Modular Budget)		
Bud	get for Entire Proposed Period of Support (not applicable with Modular Budget)		
Bude	gets Pertaining to Consortium/Contractual Arrangements (not applicable with Modular Budget)		
	raphical Sketch—Principal Investigator/Program Director (Not to exceed four pages)		
_	er Biographical Sketches (Not to exceed four pages for each – See instructions))		
	Durces		
	earch Plan		
	uction to Revised Application (Not to exceed 3 pages)		
	A-N: not to exceed 10 pages Purpose/Objectives/Specific Aims		
	Hypotheses/Research Questions		
	Significance		
	Military Relevance		
	Background/Review of Literature		
	Preliminary Studies/Progress Report		
	Research Design, Methods, and Randomization Process		
	Data Collection and Measurement		
I.	Target Sample, Sample Size, and Inclusion/Exclusion Criteria		
J.	Data Collection and Measurement		
K.	Human Subject Protection, Recruitment, Benefits, Risks, and Risk/Benefit Assessment		-
L.	Vertebrate Animals		
M	Data Analysis		
N.	Timeline		
0.	Bibliography		
Ched	cklist		
	endix (Five collated sets. No page numbering necessary for Appendix.)		eck if
			oendix is luded
	ndices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited.	] ""	iuucu
Numb	er of publications and manuscripts accepted for publication (not to exceed 10)		

Other items (list):

## PHS 416-1 Pages for Graduate Research Awards

(For Student Applicants)

To be completed in addition to selected PHS398 forms (see table on page 10)

**Scholastic Performance (Form Page 4)** 

**Background (Form Page 5)** 

**Biographical Sketch of Sponsor (Form Page 7)** 

**Facilities and Commitment (Form Page 8)** 

PART I (Form Pages 1 to 6, 9)

# TSNRP Graduate Research Award Application Scholastic Performance

NAME OF APPLICANT (Last, first, middle initial)

(To be completed by applicant--follow PHS 416-1 instructions.)

23. SCHOLASTIC PERFORMANCE: **Predoctoral** applicants: List by institution and year all undergraduate and graduate courses with grades. **Postdoctoral** applicants: List by institution and year all undergraduate courses and graduate scientific and/or professional courses germane to the training sought under this award with grades. Complete block at bottom of page, if applicable. **Senior** applicants: Omit this page.

training sought under this award with grades. Complete block at bottom of page, if applicable. <b>Senior</b> applicants: Omit this page.						
	SCIENCE			OTH		
YEAR	COURSE TITLE	GRADE	YEAR	COURS	SE TITLE	GRADE
Explain marking system if Graduate Record Examina	other than 1-100 or <i>i</i> tion, <i>if available</i> .	A, B, C, D, F. Show	level required for	passing. <b>Predoctor</b>	ral applicants state p	performance on
PHS 416-1 (Rev. 11/02)		Forr	n Page 4			

PHS 398 (Rev. 11/02) Page \_\_\_\_\_ **Form Page 3** 

PART I (Form Pages 1 to 6,9)

# TSNRP Graduate Research Award Application **Background**

NAME OF APPLICANT (Last, first, middle initial)

Dackground	
(To be completed by applicantfollow PHS 416-1 instructions.)	
24. PRIOR AND/OR CURRENT TSNRP SUPPORT. List type (individual ar	nd/or institutional), level (pre or post), dates, and grant or award numbers.
OF A CAREMIC AND PROFESCIONAL HONORS. Include all cabalcrakin	- Australas de la Companya de la Companya de Companya
25a. ACADEMIC AND PROFESSIONAL HONORS. Include all scholarship awards (NSF, Woodrow Wilson, etc.), dates, and grant or award numbers. I	ist current professional societies, if applicable
awards (1101, 1100drow 11115011, ctc.), dates, and grant of award numbers.	List current professional societies, if applicable.
25b. TITLE(S) OF THESIS/DISSERTATION(S)	
26. NAME OF DISSERTATION ADVISOR OR CHIEF OF SERVICE	TITLE, DEPARTMENT, AND INSTITUTION
(If reference report not included, explain why not.)	
27. APPLICATION FOR CONCURRENT SUPPORT	
NO YES Using format below, list all support (training, re	esearch, supplies, travel, etc.) applied for that would run concurrently with
the period covered by this application. Include the t	ype, dates, source, and amount.
Туре:	Dates:
Source:	Amount::
Type:	Dates:
Source:	Amount::
Туре:	Dates:
Source:	Amount::
Type:	Dates:
Source:	Amount::
Type:	Dates:
Source:	Amount::

#### **BIOGRAPHICAL SKETCH**

Provide the following information for the sponsor (and co-sponsor, if applicable) in the format indicated. Use a separate Form Page 7 for each biographical sketch submitted. **DO NOT EXCEED FOUR PAGES** Also, complete items 9 through 14 on Form Page 1, and items 19, 20 and 21 on Form Page 2.

NAME OF SPONSOR (CO-SPONSOR)	POSITION TITL	E	
EDUCATION/TDAINING (Besign with because weather within a series			do no oddo odo vol Avojnin v V
EDUCATION/TRAINING (Begin with baccalaureate or other initial profes	ssional education, suc	n as nursing, and inclu	de postdoctorai training.)
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
	l		

NOTE: The Biographical Sketch may not exceed four pages. Items A and B may not exceed two of the four-page limit.

- **A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- **B. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.
- **C. Research Support.** List selected ongoing or completed (during the last three years) research projects (Federal and non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the sponsor (co-sponsor) identified above.

PART II (Form Pages 7 to 9) Continued Name	e of Applicant (Last, first, midd	dle):		
BIOGRAPHICAL SKETCH  Provide the following information for the sponsor (co-sponsor). DO NOT EXCEED FOUR PAGES.				
NAME OF SPONSOR (CO-SPONSOR)	POSITION TITL	E		
EDUCATION/TRAINING (Begin with baccalaureate or other initial pro	ofessional education, such as	nursing, and include p	ostdoctoral training.)	
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY	

PHS 416-1 (Rev. 06/02) Page \_\_\_\_\_ (Form Page 7)

PART II (Pages 7 to 9)

PHS 416-1 (Rev. 11/02)

# TSNRP Graduate Research Award Application Facilities and Commitment

(Form Page 8)

(To be completed by sponsor--follow PHS 416-1 instructions.)

32. Identify the research and research training support available to the	ne sponsor and the applicant during period of pr	oposed award.	
33. SPONSOR'S PREVIOUS FELLOWS/TRAINEES			
Give total number of pre- and postdoctoral individuals and prov	ide information on a representative five. List the	neir present employ	ing organizations
and position titles or occupations.	·	,	0 0
FACILITIES AND COMMITMENT STATEMENT			
In the space below and on continuation pages, complete the following	items. Identify each item by number and title.		
34. Training Plan, Environment, Research Facilities.			
Describe the research training plan for the applicant, Include suc			
and scientists. Describe the research environment and available			
groups evaluate the applicant and the proposed training. Indicate the relationship of the proposed research training to the applicant's career.  Describe the skills, techniques, etc., that the applicant will learn and relate these to the applicant's career goals.			
35. Number of Fellows/Trainees to be Supervised During the Fellowship. Indicate Pre-or Postdoctoral.			
36. Applicant's Qualifications and Potential for a Research Career.			
• •			
37. Human Subjects/Vertebrate Animals Use and Description.			
38. CERTIFICATION: We, the undersigned, certify that the statem	ents herein are true, complete, and accurate t	to the best of our k	nowledge. If this
application results in an award, appropriate training, adequate facilitie			
Public Health Service terms and conditions of award. We are aware	that any false, fictitious, or fraudulent statemen	t or claim may subj	ect us to criminal,
civil, or administrative penalties.	<u></u>	1	
SIGNATURE	TYPED NAME	OFFICE	DATE
		TELEPHONE	
SPONSOR			
		I	
DEPARTMENT HEAD			
OFFICIAL SIGNING FOR SPONSORING INSTITUTION			

Page \_\_\_\_\_

## PHS 416-1 Pages for Research Fellow Awards

To be completed in addition to selected PHS398 forms (see table on page 10)

Form Page 2

**Table of Contents (Form Page 3)** 

**Scholastic Performance (Form Page 4)** 

**Background (Form Page 5)** 

Research (Form Page 6)

**Biographical Sketch of Sponsor (Form Page 7)** 

**Facilities and Commitment (Form Page 8)** 

PHS 398 (Rev. 11/02) Page \_\_\_\_\_ **Form Page 3** 

TSNRP	Research Fel	low Award Applica	NAME OF APPLICANT (Last,	first, middle initial)	
		follow PHS 416-1 instr			
16. APPLICANT'S EDUC	ATION				
DEGREE MONTH(mm)	YEAR (yyyy)	FIELD	INS	TITUTION	MENTOR
17. APPLICANT'S TRAIN					
ACTIVITY/ OCCUPATION	BEGINNING DATE (mm/yy)	ENDING DATE (mm/yy)	FIELD	INSTITUTION/COMPANY	SUPERVISOR/EMPLOYER
000017111011	<i>5,</i> (1.2 (1.11.11, yy))	D/(12 (!!!!!#yy)	11225	interine the file of the file	GGI EITVIGGIVEINI EGTEIT
18. GOALS FOR FELLON	WSHIP TRAINING	AND CAREER			
			SPONSOR		
19. NAME AND DEGREE	E(S)				
20. POSITION/RANK					
21. RESEARCH INTERE	STS/AREAS				
		RES	SEARCH PROPOSAL		
22. DESCRIPTION		N_C	PEAROTT NOT GOAL		

### **Table of Contents**

Page Numbers
(Number pages consecutively at the bottom throughout

		1-3
	astic Performance (Form Page 4)	4
	ground (Form Page 5)	5
	arch (Form Page 6)	
	Summary	
b.	Doctoral Dissertation	
_ C.	Publications	
	ed Application	
	ng Plan	
	Activities Under Award	
b.	Training Proposal	
	(1) Background and Career Goals of the fellow	
	(2)·Significance to Military Nursing Research	
	(3) Specific Aims of the Training (Not to exceed 10 pages)	
	(4) Mentoring Plan	
	(5) Final Product	
	(6) Literature Cited	
C.	Respective Contributions	
d.	Selection of Sponsor and Institution	
e.	Responsible Conduct of Research	<del></del>
Biogra	aphical Sketch of Research Fellow (PHS 398 form)	
Section	on 2 — Sponsor	
Biogra	aphical Sketch (Form Page 7)	
	ies and Commitment Statement (Form Page 8)	
	raining Plan, Environment, Research Facilities	<del></del>
	umber of Fellows/Trainees to be Supervised	
	pplicant's Qualifications and Potential	<del></del>
	uman Subjects	
	ertebrate Animals	
	on 3 — Budget	
	ed Budget for Initial Budget Period (PHS 398 form)	
	et for Entire Proposed Period of Support (PHS 398 form)	
	ets Pertaining to Consortium/Contractual Arrangements (PHS 398 form)	
_	klist (PHS 398 form)	
	Items (list):	
	· /	
	ersonal Data Page for Applicant (PHS 398 form)	
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•		
	on 4 — Annendix	
Section	on 4 — Appendix  Ricollated sets - No page numbering necessary - Not to exceed 3 publications: 2 for pr	adoctoral candidates
Section (3	on 4 — Appendix B collated sets. No page numbering necessary. Not to exceed 3 publications; 2 for properties if Appendix is included	edoctoral candidates.,

# TSNRP Research Fellow Award Application Scholastic Performance

(To be completed by applicant--follow PHS 416-1 instructions.)

NAME OF APPLICANT (Last, first, middle initial)

23.	SCHOLASTIC PERFORMAN	NCE: Predoctoral	applicants: L	List by institution	and year all	undergraduate	and graduate co	ourses with	grades
	Postdoctoral applicants: Lis	st by institution and	year all underg	graduate courses	and graduate	scientific and/or	professional cou	rses germane	e to the
	training sought under this awa	ard with grades. Co	mplete block at	bottom of page, if	applicable. Se	enior applicants:	Omit this page.		

	SCIENCE			OTHER	
EAR	COURSE TITLE	GRADE	YEAR	COURSE TITLE	GRAD

Explain marking system if other than 1-100 or A, B, C, D, F. Show level required for passing. **Predoctoral** applicants state performance on Graduate Record Examination, *if available*.

PART I (Form Pages 1 to 6,9)

# TSNRP Research Fellow Award Application **Background**

NAME OF APPLICANT (Last, first, m	niddle initial)

Background	
(To be completed by applicantfollow PHS 416-1 instructions.)	
24. PRIOR AND/OR CURRENT TSNRP SUPPORT. List type (individual and	nd/or institutional), level (pre or post), dates, and grant or award numbers.
OF A CADEMIC AND DEOFFCCIONAL HONORS. Include all calculates	Avainanting fallowships and development awards ladicate covers of
25a. ACADEMIC AND PROFESSIONAL HONORS. Include all scholarship awards (NSF, Woodrow Wilson, etc.), dates, and grant or award numbers. I	s, traineesnips, fellowsnips, and development awards. Indicate source of List current professional societies, if applicable.
25b. TITLE(S) OF THESIS/DISSERTATION(S)	
26. NAME OF DISSERTATION ADVISOR OR CHIEF OF SERVICE (If reference report not included, explain why not.)	TITLE, DEPARTMENT, AND INSTITUTION
27. APPLICATION FOR CONCURRENT SUPPORT  Using format below, list all support (training, respectively) the period covered by this application. Include the	esearch, supplies, travel, etc.) applied for that would run concurrently with type, dates, source, and amount.
Type: Source:	Dates: Amount::
Type: Source:	Dates: Amount::
Type: Source:	Dates: Amount::
Type: Source:	Dates: Amount::
Type: Source:	Dates: Amount::

### TSNRP Research Fellow Award Application

### Research

(To be completed by applicant--follow PHS 416-1 instructions.)

- 28. RESEARCH EXPERIENCE
  - a. Summary
  - b. Doctoral Dissertation
  - c. Publications (published, accepted, submitted, or in preparation)
- 29. REVISED APPLICATION
- 30. TRAINING PLAN

a. Approximate percentage of proposed award time in activities identified below. (See instructions.)

Year	Research	Course Work	Teaching	Clinical	
First					

- b. Training Proposal
  - Background and Career Goals of the fellow
  - Significance to Military Nursing Research
  - Specific Aims of the Training
  - Mentoring Plan
  - Final Product
- c. Respective Contributions
- d. Selection of Sponsor and Institution
- e. Responsible Conduct of Research

NAME OF APPLICANT (Last, first, middle initial)

#### **BIOGRAPHICAL SKETCH**

Provide the following information for the sponsor (and co-sponsor, if applicable) in the format indicated. Use a separate Form Page 7 for each biographical sketch submitted. **DO NOT EXCEED FOUR PAGES** Also, complete items 9 through 14 on Form Page 1, and items 19, 20 and 21 on Form Page 2.

NAME OF SPONSOR (CO-SPONSOR)	POSITION TITL	POSITION TITLE			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)					
INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY		
INSTITUTION AND LOCATION	(if applicable)	ILAN(S)	TILLED OF STODE		

NOTE: The Biographical Sketch may not exceed four pages. Items A and B may not exceed two of the four-page limit.

- **A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- **B. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.
- **C. Research Support.** List selected ongoing or completed (during the last three years) research projects (Federal and non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the sponsor (co-sponsor) identified above.

PART II (Pages 7 to 9)

### **TSNRP Research Fellow Award Application Facilities and Commitment**

NAME OF APPLICANT (Last, first, middle initial)

(To be completed by sponsor--follow PHS 416-1 instructions.)

32.	Identify the research and research training support available to the sponsor and the applicant during period of proposed award.
33.	SPONSOR'S PREVIOUS FELLOWS/TRAINEES Give total number of pre- and postdoctoral individuals and provide information on a representative five. List their present employing organizations and position titles or occupations.
In ti	CILITIES AND COMMITMENT STATEMENT  the space below and on continuation pages, complete the following items. Identify each item by number and title.  Training Plan, Environment, Research Facilities.  Describe the research training plan for the applicant, Include such items as classes, seminars, and opportunities for interaction with other groups and scientists. Describe the research environment and available research facilities and equipment. Include information that will help reviewing groups evaluate the applicant and the proposed training. Indicate the relationship of the proposed research training to the applicant's career.  Describe the skills, techniques, etc., that the applicant will learn and relate these to the applicant's career goals.
35.	Number of Fellows/Trainees to be Supervised During the Fellowship. Indicate Pre-or Postdoctoral.
36.	Applicant's Qualifications and Potential for a Research Career.
37	Human Subjects/Vertebrate Animals Use and Description

38. CERTIFICATION: We, the undersigned, certify that the statements herein are true, complete, and accurate to the best of our knowledge. If this application results in an award, appropriate training, adequate facilities, and supervision will be provided, and we accept the obligation to comply with the Public Health Service terms and conditions of award. We are aware that any false, fictitious, or fraudulent statement or claim may subject us to criminal, civil, or administrative penalties.

SIGNATURE	TYPED NAME	OFFICE TELEPHONE	DATE
		TELEPHONE	
SPONSOR			
DEPARTMENT HEAD			
OFFICIAL SIGNING FOR SPONSORING INSTITUTION			

PHS 416-1 (Rev. 11/02) (Form Page 8) Page \_\_\_\_

# **APPENDIX D**

### SAMPLE TIMELINE

The sample below was created for a study employing survey and focus group methodology. Investigators should create timelines that are **specific to the proposed research.** 

	YEAR 1			YEAR 2				
	Oct-	Jan-	Apr-	Jul-	Oct-	Jan-	Apr-	Jul-
	Dec	Mar	Jun	Sep	Dec	Mar	Jun	Sep
Recruit & Hire								
Study Personnel								
Print Questionnaires								
& Create Database								
Establish Liaison								
With Units								
Prepare								
Questionnaire								
Mailing								
Send 1 <sup>st</sup> Mailing of								
Questionnaires								
Send								
Reminder Postcards								
Send 2 <sup>nd</sup> Mailing of								
Questionnaires								
Obtain APFT Results								
& Enter in Database								
Scan Questionnaires								
Into Database								
Questionnaire Data								
Cleaning								
Questionnaire &								
APFT Data Analysis								
Data Interpretation								
Focus Group Training								
And Planning								
Focus Groups								
Focus Group Data								
Interpretation								
Identify Intervention								
Strategies to								
Increase Exercise								
Participation								
Report & Manuscript								
Preparation								

Timeline provided courtesy of COL Laura R. Brosch, ANC

### **APPENDIX E**

#### SELECTED REFERENCES

### **Human Subjects Protection**

*DoD Directive 3216.2*, protection of human subjects and adherence to ethical standards in DoD-supported research.

DoD Directive 6000.8, Funding and Administration of Clinical Investigation Programs.

DoD Instruction 1100.13, Surveys of DoD Personnel.

*Title 21 Code of Federal Regulation (CFR) 50, 56, 312, 314*, Good Clinical Practice (Protection of human subjects; Institutional Review Boards; Investigational new drug application; Applications for FDA approval to market a new drug).

Title 32 CFR 219, Human Subjects Protection.

Title 45 CFR 46, Subparts A, B, C, and D, Protection of Human subjects.

Title 5 U.S. Code 5536, Extra pay for extra services prohibited.

Title 10 U.S. Code 980, Limitation on use of humans as experimental subjects.

Title 24 U.S. Code 30, Payments to donors of blood for persons undergoing treatment at Government expense.

Health Affairs Policy 97-033, 3 Mar 1997, "Policy For External Peer Review For Defense Health Program Extramural Medical Research Involving Human Subjects".

### Air Force Regulations

AFI 40-402, 1 Sep 2000, Clinical Investigation and Human Test Subjects in the Medical Service.

#### **Army Regulations**

AR 40-38, Clinical Investigation Programs.

AR 70-25, Use of volunteers as subjects of research.

### Navy Regulations

SECNAV INST 3900.39B, 27 Feb 1984, Protection of Human Subjects.

NAVMEDRSCHCEN INST 3900.6a.

### **Non-human Animal Subjects**

*NIH Publication No. 86-23*, Guide for the Care and Use of Laboratory Animals.

DoD Directive 3216.1, The Use of Animals in DoD Programs.

Title 9 CFR, Chapter 1, Subchapter A (Animal Welfare), Parts 1-4.

Access these documents online through <a href="http://www.usuhs.mil/tsnrp/links/management.html">http://www.usuhs.mil/tsnrp/links/management.html</a>

### **APPENDIX F**

### RESEARCH CONSULTANTS/SPECIALITY LEADERS

#### **ARMY**

Laura R. Brosch, COL, USA, AN PhD, RN Dep. Chief of Staff for Reg. Compliance US Army Medical Research & Materiel Command E-mail: laura.brosch@det.amedd.army.mil

### NAVY

Charles A. Vacchiano, CAPT, NC, USN PhD, CRNA Head, Biomedical Sciences Department Naval Aerospace Medical Research Laboratory E-mail: evacc@namrl.navy.mil

### **AIR FORCE**

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Deputy Commander, Clinical Research Wilford Hall Medical Center
E-mail: elizabeth.bridges@lackland.af.mil